

## UNITED STATES DEPARTMENT OF COMMERCE

Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231

APPLICATION NO.	FILING DATE	,	FIRST NAMED INVENTOR			TORNEY DOCKET NO.	
09/431,51	9 11/01/	99 C	HUNG		S	AH0948Q	
PALAIYUR S KALYANARAMAN			HM12/0329 7		E	EXAMINER	
PATENT DE	5 KALYANARA PT K-6-1 19	AMAN aca			LEVY, N		
2000 GALLOPING HILL ROAD		ROAD			ART UNIT	PAPER NUMBER	
KENILWORTH NJ	H NJ 07033-	J 07033-0530			1616	8	
				-	DATE MAILED:	03/29/01	

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trad marks** 

	TA 17 47 4 A4 -	/	· · · · · · · · · · · · · · · · · · ·	·	
Office Action Summary	Application No.	79 Applicant(s)	Applicant(s) // UNG efw		
Office Action Summary	Examiner	Cery	Group An Unit	8	
—The MAILING DATE of this communication appea	ars on the cover si	neet beneath the	correspondence a	address	
P ri d for Reply	5				
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET OF THIS COMMUNICATION.	TO EXPIRE	MONTH(	S) FROM THE MA	ILING DATE	
<ul> <li>Extensions of time may be available under the provisions of 37 CFR from the mailing date of this communication.</li> <li>If the period for reply specified above is less than thirty (30) days, a relative to reply is specified above, such period shall, by default</li> <li>Failure to reply within the set or extended period for reply will, by sta</li> </ul>	reply within the statutory	y minimum of thirty (30 HS from the mailing d	)) days will be conside ate of this communica	red timely.	
Status 7	14/n1	1	•		
Tesponsive to communication(s) filed on	//////		•	•	
☐ This action is <b>FINAL</b> .	′/				
<ul> <li>Since this application is in condition for allowance except accordance with the practice under Ex parte Quayle, 19</li> </ul>			o the merits is clo	osed in	
Disp sition of Claims			•		
Caclaim(s)		is/are	pending in the ap	plication.	
Of the above claim(s) 21 - 92			withdrawn from co		
□ Claim(s)			allowed.		
$\mathcal{G}_{\text{Glaim(s)}} = 1 - 2\mathcal{D}$	· · · · · · · · · · · · · · · · · · ·	is/are	rejected.		
☐ Claim(s)			objected to.		
□ Claim(s)		are s	ubject to restriction	or election	
Application Papers		requi	rement.		
☐ See the attached Notice of Draftsperson's Patent Drawin	ng Review, PTO-94	3.	•		
☐ The proposed drawing correction, filed on	is 🗆 appro	oved 🗆 disapprov	ed.		
☐ The drawing(s) filed on is/are obje	cted to by the Exam	iner.	•	•	
☐ The specification is objected to by the Examiner.		•			
☐ The oath or declaration is objected to by the Examiner.					
Pri rity under 35 U.S.C. § 119 (a)-(d)					
<ul> <li>□ Acknowledgment is made of a claim for foreign priority to</li> <li>□ All □ Some* □ None of the CERTIFIED copies oo</li> <li>□ received.</li> </ul>					
☐ received in Application No. (Series Code/Serial Number	oer)	y-100.00	·		
$\hfill\Box$ received in this national stage application from the In	ternational Bureau (	PCT Rule 1 7.2(a)	).		
*Certified copies not received:			·	v	
Attachm nt(s)	$\mathcal{L}$			•	
Information Disclosure Statement(s), PTO-1449, Paper	No(s)	☐ Interview Sun	nmary, PTO-413		
Notice of Reference(s) Cited, PTO-892		rmal Patent Applica	ation, PTO-152		
☐ Notice of Draftsperson's Patent Drawing Review, PTO-9	48	☐ Other			
Offic	ce Acti n Summary	<i>l</i>			

U. S. Patent and Trademark Office PTO-326 (Rev. 9-97)

Art Unit: 1616

Receipt is acknowledged of IDS, Request for Time, and Amendment of 8/29/00; 1/04/01 and 1/04/01 respectively.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 21-42 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in Paper No. 3.

Claims 1-13, 16, 17 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Deasy 4874612.

The rejection of record is maintained.

Two formulations in one implant, of anabolic agents, are implants effective in cattle (Col.3, line 36-50). The active varies in concentration of the dual formulation (Col 3, lines 4-8). Added components do NOT interfere with the activity of the dual action A+B anabolic agents, which are those of the instant claims 9, 10.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deasy and Porter-GB 2397484 in view of Hornykiewytsch et al .

The rejection of record is maintained.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al 2546759.

The rejection of record is maintained.

Art Unit: 1616

Claims 1-5, 7-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Ivy et al 4670249.

Growth hormones and Zeranol are implanted in cattle (see Claim 2) to increase feed efficiency and rate of growth (Claim 7) subcutaneously (Claim 13). Immediate effects attributable to growth hormone are seen (Table 3 week 1, F/G) while Zeranol is effect uses long term (final, F/G, Table 4). Dosages formulations are in the instant range (Col. 4, lines 3-21). Diluents are as are known in the art-The implant is artisan recognized forms (Col. 4, lines 22-30).

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deasy in view of Ivy et al, O'Callaghan et al '86 Sivaramakrishnan-5219572 and Kim et al 5744163.

Deasy (above) provides the instant implants, but not all attributes of the instant concentration, diluents and polymers are specified. But Ivy (above) shows use, if desired of 2 different anabolic agents, in any known implants (Col. 4, lines 22-29), thus, clearly in Deasy. The instant specification provides no guidance as to meaning of "instant" except, 28. Ivy shows efficacy at 1 week. The instant specification provides no guidance in accord with the claims, of the concentration of active anabolic agent, (Ivy does) or of the amount of active with polymer formulation (Deasy does). O'Callaghan further shows the same compound can be provided in show and quick acting anabolic implants; inclusive of oestradiol with oestradiol (p. 427) or oestradiol with trenbolone acetate anabolic efficacy is seen. Sivaramakrishnan show the diluents Example 8. The active (Col.5, top) is 1-70% of the formulation (instant claim 19 is 1-8%).

Art Unit: 1616

Excipients are used. <u>Kim</u> show similar implants, utilizing ethyl cellulose, equivalent to the Deasy, .

Ivy wax (Col.3, lines 10-15).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made desiring to improve growth, with reduction in animal handling, would use Deasy, modified with particular ingredients and concentrations as are known in the art, in order to maximize compatibility, health, ease of administration and efficacy.

Ivy and O'Callahan teaches one having ordinary skill in the art would be motivated to perform these modifications, in order to increase efficacy. The particular %mix of active, is a function of the compatibility of these components, and length of time to market.

The selection of each component is a result effective parameter chosen to obtain the desired effects. It would be obvious to vary the nature of each ingredient to optimize the effects desired.

There is no unusual and/or unexpected results obtained since the prior art is well aware of the various forms of implants, excipients, coatings, delivery methods, diluents, and active anabolic agents and the concentrations and amounts required. Applicant provides no objective of evidence of any criticality in these regards. Further, the open claim language permits of multiple interpretation of the relative amounts of agent to agent, agent to formulation, and formulation to formulation, to say nothing of the interpretation possible to the meaning of anabolic. However, although examiner does not find clear stipulation as to the meaning of claims 2-4 and 11 and 12,

Art Unit: 1616

in the specification one of ordinary skill in the art of growing cattle would negate the bases for continuing of non enabling or scope first paragraph rejections.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neil Levy whose telephone number is (703) 308-2412. The examiner can normally be reached on Tuesday to Friday from 7:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees, can be reached on (703) 308-4628. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235. Willey

Levy:mv

March 23, 2001